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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.  | CONFIRMATION NO. |
|--|-------------|----------------------|----------------------|------------------|
| 09/787,792   | 06/22/2001  | Tobias Meyer         | 0459-0570P           | 9673             |
| 2292   | 7590        | 04/06/2004           | EXAMINER             |                  |
| BIRCH STEWART KOLASCH & BIRCH<br>PO BOX 747<br>FALLS CHURCH, VA 22040-0747 |             |                      | WESSENDORF, TERESA D |                  |
|  |             |                      | ART UNIT             | PAPER NUMBER     |
|  |             |                      | 1639                 |                  |

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |  |                     |  |
|------------------------------|------------------------|--|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> |  | <b>Applicant(s)</b> |  |
|                              | 09/787,792             |  | MEYER, TOBIAS       |  |
|                              | <b>Examiner</b>        |  | <b>Art Unit</b>     |  |
|                              | T. D. Wessendorf       |  | 1639                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6,11-14,23-25 and 47-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,11-14,23-25 and 47-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

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**DETAILED ACTION**

***Election/Restrictions***

***Response to Arguments***

Applicants argue that the non-elected species of claim 12 should be rejoined with the elected claims because claim 12 is generic. In response, claim 12 will be rejoined with the elected species.

***Status of Claims***

Claims 7-10, 15-22 and 26-46 have been cancelled.

Claims 1-6, 11-14, 23-25 and 47-49 are under examination.

***Specification***

The abstract of the disclosure is objected to because it is too long and contains the phraseology "comprises" often used in patent claims. Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities for the reasons advanced in the last Office action.

***Response to Arguments***

In view of the submission of Figure 1E obviates the objection to the specification. However, the newly submitted Drawings do not contain Figs. 4 A-D as disclosed at pages 5-6 of the instant disclosure.

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***Claim Rejections - 35 USC § 112, first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 4, 47 and 48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons advanced in the last Office action.

***Response to Arguments***

Applicants argue that it is inherent that in a host cell system, these conjugates will be expressed separately since they are distinct conjugates. Applicant argues that claims 3 and 5 have been amended to clarify the claim language.

In response, applicants' argument as to inherency is contradictory to applicants' prior response referencing page 25, lines 6-10 of the specification. Furthermore, separate

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expression is a probable inherency. Since this fusion proteins can be expressed as a unit fusion protein.

The rejection with respect to the claimed term "derived" and claim 48 is moot with the amendments to the claims.

Claims 1-6, 11-14, 23-25 and 47-49 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for GFP as the detectable group and isoforms of CaMKII  $\alpha$  and  $\beta$ , does not reasonably provide enablement for a first and second heterologous protein conjugates, fragments of the protein and any type of cell for reasons advanced in the last Office action.

#### ***Response to Arguments***

Applicants argue that claim 1 has been amended to incorporate CaMKII alpha and beta. Applicants made reference that the examiner indicated that this will be allowable. However, applicants' response is not commensurate with the amended claims which does not recite the argued CaMKII alpha and beta.

#### ***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Newly amended claims 1-6, 11, 13-25 and 46-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons set forth in the last Office action.

***Response to Arguments***

In view of the amendments to the claims and applicants' arguments the rejections of the claims in the last Office action no longer apply.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-6, 11, 13-25 and 46-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Knippschild et al (Oncogene, 1997) for reasons set forth in the last Office action.

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***Response to Arguments***

In view of the amendments to the claims, the rejection under 102 is moot.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 11, 13-25 and 46-49 rejected under 35 U.S.C. 103(a) as being unpatentable over Knippschild in view of Shirai(Jpn. J. Pharmacol.) or Oancea et al (The Journal of Cell Biology) for reasons set forth in the last Office action.

***Response to Arguments***

In view of the amendments to the claims the rejection is moot.

Claims 1-6, 11-14, 23-25 and 47-49 are rejected under 35 U.S.C. 102(a) as being anticipated by applicants' disclosure.

Applicant's disclosure discloses at e.g., page 26, line 9 that "we expressed GFP-CaMKII together....." Throughout the Procedures in the specification, reference to "we" has been

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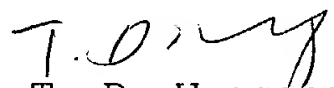
constantly used. It is therefore unclear as to whether the invention is made by the sole inventor or with another inventor(s).

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571)272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-0812. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
T. D. Wessendorf  
Primary Examiner  
Art Unit 1639

tdw  
April 2, 2004